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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,715	09/18/2003	Dimitrios Manoussakis	P-5808	4404

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EXAMINER	
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ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
11/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,715	MANOUSSAKIS ET AL.	
	Examiner	Art Unit	
	P. Kathryn Wright	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16-18,20-24,26-28 and 30-32* is/are pending in the application.

4a) Of the above claim(s) *1-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14, 16-18, 20-24, 26-28, 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 08, 2008 has been entered.

Status of the Claims

2. This action is in response to papers filed October 08, 2008 in which claims 14, 20-21 and 32 were amended, claims 25, 29 were canceled, and claims 1-13, 33-86 are currently withdrawn. The amendments have been thoroughly reviewed and entered.

Applicant's arguments have been thoroughly reviewed. Any objection/rejection not repeated herein has been withdrawn by the Office.

Claims 14, 16-18, 20-24, 26-28, and 30-32 are under prosecution.

Claim Objections

3. Claims 14, 16-18, 20-24, 26-28, and 30-32 are objected to because of the following informalities: the recitation of the thixotropic gel located in the container is redundant since the preamble recites the container comprises, *inter alia,* a thixotropic gel. The Office recommends Applicant delete "in the container" in line 4 of claim 14. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 14, 16-18, and 20-24, 26-28 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Kessler (US Patent No. 4,350,593).

Kessler teaches a container (tube 12) having an upper end, a closed lower end, and a sidewall between the upper and lower ends having inner and outer walls (see col. 3, lines 53- Figs. 2-4). The tube includes a pierceable closure 14 therein (claim 31).

The only structure with respect to the claimed container and thixotropic gel in the claim is the recitation of a thixotropic gel located in contact with a portion of the inner wall of the container. The thixotropic gel of Kessler is specifically cited in Applicant's instant specification as capable of being advantageously used in the invention, see par. [0033] of the instant specification. Kessler teaches a thixotropic gel 22 located inside at the closed lower end of the container contacting a portion of the inner wall (col. 1, line 56- col. 2, line 2; col. 3, line 54- col. 4, line 6; see also Figs. 2-3). Therefore, since the claimed and prior art gels are identical or substantially identical in structure or composition they must necessarily exhibit the same rheological properties under the same conditions. That is, the first region of the gel of Kessler inherently comprises:

a first region with at least about 80 vol. % of the gel (claim 14), the imaginary upper boundary exhibits a best fit plane within 10 degrees of a plane perpendicular to

the longitudinal axis of the tube (claim 16), the distance between the first and second regions being between 8 to 21 mm (claims 17-18), the first region comprises about 80 to 95 vol. % of the gel (claim 20), the interior surface of the thixotropic gel at the intersection of the first and second regions exhibits a radius of curvature between about 4 and about 8 mm (claim 21), wherein a best-fit plane to the exposed surface of the first region facing the interior of the container exhibits an angle of 25 ° or less with a plane substantially perpendicular to the longitudinal axis of the container (claim 22), the exposed surface of the second region facing the interior of the container defines a best-fit plane exhibiting a 45 to 90° angle with a plane substantially perpendicular to the longitudinal axis of the container (claim 23), the best-fit plane to the exposed surface of the first region facing the interior of the container exhibits an angle of 90 to 140° with the best-fit plane to the surface of the second region facing the interior of the container (claim 24), wherein along a plane perpendicular to the longitudinal axis of the container located halfway between the average height of the exposed surface of the first region and the uppermost point of the second region, the second region exhibits 80 to 140° circumferential contact with the inner surface (claim 26), wherein the entirety of the second region exhibits less than 180° circumferential contact with the inner wall (claim 27) and, wherein the entirety of the second region exhibits less than 120° circumferential contact with the inner wall (claim 28).

Response to Arguments

6. Applicant's arguments filed November 27, 2007 have been fully considered but they are not persuasive.

In response to the previous rejection of claims 14, 16-18, and 21-32 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kessler (US Patent No. 4,350,593), Applicant argues that claim 14 is directed to a specific geometry (and not a composition or structure) for a thixotropic gel disposed in a container which overcomes potential gel movement issues. Applicants assert that Kessler is completely silent in regard to the vol.% of gel in the first region.

The Examiner respectfully disagrees. As discussed above, the thixotropic gel of Kessler is specifically cited in the instant specification as capable of being advantageously used in the invention, see par. [0033] of the instant specification. The Examiner asserts that the claimed and prior art gels are identical or substantially identical in structure or composition. Therefore, the claimed and prior art gels must exhibit the same rheological properties under the same conditions, that is, the first region of Kessler must necessarily or inherently comprises the geometry of the gel as recited in claims 14, 16-18, 20-24, and 26-28.

In addition, Applicant's specification recites the desired geometry of gel may be provided by disposing the thixotropic gel into the tube using a nozzle, then centrifuging the tubes at a particular angle and speed to provide the desired geometry, see paragraph [0035]. Note the particular angle and speed is not disclosed in the original specification. Likewise, Kessler teaches filling container with a barrier material such that the barrier material 22 is disposed with the surface 23 forming other than a plane perpendicular to the axis A of the tube 12, see Fig. 2. Kessler teaches the manner of making the invention includes introducing the barrier material 22 into the container, then testing for its bleed and yield stress (see Example 1). This test comprises storing the

assembly 10 (i.e., thixotropic gel in the container 12) for a period of time and then ultra-centrifuging an aliquot of the barrier material 22. Thus, the gel of Kessler must inherently comprise geometry recited in claims 16-18, 20-24, 26-28, since the claimed gel and that of Kessler are introduced into the container and centrifuged.

Applicant also argues that Kessler fails to acknowledge or teach the importance of the vast majority of the gel be at, or near, the bottom of the tube (i.e. in the first region).

The Examiner respectfully disagrees. Kessler recognizes that the barrier 22 may not flow immediately under normal centrifugal forces if the upper surface 23 is a plane perpendicular to the axis A of the tube 12, (i.e., upper surface is flat), see col. 4, lines 21-38. Kessler states "[t]his is because the shear stress developed under the preferred normal centrifugal forces is less than the yield stress of the barrier material and is due to the symmetry of the configuration of the disposed barrier 22. Under such circumstances, increasing the centrifugal force is not desirable or practical since it may result in the rupture of cellular blood components with the consequent release of cellular fluids or may not be possible due to limitations of available centrifuging equipment. To overcome this situation, the preferred assembly of the invention comprises one as illustrated in the assembly 10 wherein barrier material 22 is disposed as shown in FIG. 2 with the surface 23 forming other than a plane perpendicular to the axis A of the tube 12." Emphasis added. Thus, contrary to Applicant's assertion, Kessler does recognize the geometry or shape of the gel has a significant effect on the movement of the gel during centrifugation and separation performance of the gel barrier. Kessler recognizes the importance of the vast majority of the gel be at or near the bottom of the tube with a

portion of the gel extending upward onto the inside surface so as overcome the yield stress of the barrier material and cause gel movement at the earliest possible stage of centrifugation so as to avoid rupture of cellular blood components.

Response to Declaration under 37 CFR 1.132

The declaration by co-inventor, Dimitrios Manoussakis, under 37 CFR 1.132 filed October 08, 2008 is insufficient to overcome the rejection of claims 14, 16-18, 20-24, 26-28, and 30-32 based upon the previous rejection of claims 14, 16-18, and 21-32 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kessler (US Patent No. 4,350,593) as set forth in the last Office action because: the Examiner has reconsidered the Kessler reference and the outstanding claims are not rejected under 103(a), since Kessler inherently teaches gel geometry disclosed in claims 14, 16-18, 20-24, and 26-28, see above rejection. Declarations containing evidence of unexpected results and failure of others are only considered in determining the issue of obviousness of claims under 35 USC 103. Such secondary considerations are not relevant to anticipation under 35 USC 102.

Therefore, for the reasons delineated above, all pending claims are rejected under 35 U.S.C. 102(b) as being anticipated by Kessler (US Patent No. 4,350,593).

Conclusion

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is (571)272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. Kathryn Wright/

Examiner, Art Unit 1797